FEB - 9 2005

K 041390

APPENDIX A

510(k) Summary

Prepared on 10 August 2004

[As required by 21 C.F.R. § 807.92(c)]

Manufacturer:	**Diamond International Corp Pty Ltd.**
Sponsor:	**Diamond Systems USA Inc.**
Address:	**Unit C, 1 Madison Street** **East Rutherford** **NEW JERSEY USA 07073**
Contact person:	**Donna Lope** **Phone: (973) 458-1221** **Fax: (973) 458-8227** **Email:** diamondsystemsusa@earthlink.net

Device name:	**Diamond MediStim & Diamond CliniStim**
Common Name:	**Muscle Stimulator**
Classification Name:	**Powered Muscle Stimulator**

Predicate Device: **Ultratone 20 (K926410)**

Description of Device: The Diamond MediStim is a powered muscle stimulator, which is an electrically powered device intended for medical purposes that repeatedly contracts muscles by passing electrical currents through electrodes contacting the affected body area. The machine uses 2 modes: VARIABLE STIM and AUTO STIM. The device has CE approval.

Intended Use: There are 6 intended uses:

- Prevention of retardation of disuse atrophy
- Increasing of blood circulation
- Muscle re-education
- Maintaining or increasing range of motion
- Immediate post surgical stimulation of calf muscle to prevent thrombosis
- Relaxation of muscle spasms

When the device is used in a manner that delivers continuous, uninterrupted pulses, it is indicated only for the relaxation of muscle spasms. The Variable Stim output mode delivers continuous, uninterrupted pulses. The Auto Stim output mode delivers bursts of pulses that are interrupted with 1 second "off" periods.

Technological Comparison: The DIAMOND MEDISTIM is substantially equivalent to the ULTRATONE. The DIAMOND MEDISTIM and the ULTRATONE have similar technological characteristics.

Non-clinical Test:

The DIAMOND MEDISTIM was compared to the ULTRATONE in terms of controls and waveforms.

The DIAMOND MEDISTIM and ULTRATONE were connected to an oscilloscope using shunts/loads to determine output levels and waveforms, and the circuit loops were tested to determine aspects such as patient leakage current. It was observed that the DIAMOND MEDISTIM was substantially equivalent to the ULTRATONE.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 9 2005

Donna M. Lope
Executive Vice President
Diamond Systems USA, Corp.
One Madison Street, Building C
East Rutherford, New Jersey 07073

Re: K041390
Trade/Device Names: Diamond MediStim and Diamond CliniStim
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: Class 2
Product Code: IPF
Dated: January 24, 2005
Received: January 25, 2005

Dear Ms. Lope:

We have reviewed your Section 510(k) premarket notification of intent to market the devices referenced above and have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the devices, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your devices are classified (see above) into either class II (Special Controls) or class III (PMA), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your devices in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your devices comply with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if

applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your devices as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your device and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, M.D., Ph.D.
Director
Division of General, Restorative, and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

APPENDIX D

Indications for Use

510(k) Number: K041390

Device Name: Diamond MediStim and Diamond CliniStim

Indications for Use:

1. Relaxation of muscle spasms;
2. Prevention or retardation of disuse atrophy;
3. Increasing local blood circulation;
4. Muscle re-education;
5. Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis; and
6. Maintaining or increasing range of motion.

When the device is used in a manner that delivers continuous, uninterrupted pulses, it is indicated only for the relaxation of muscle spasms. The Variable Stim output mode delivers continuous, uninterrupted pulses. The Auto Stim output mode delivers bursts of pulses that are interrupted with 1 second "off" periods.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Melkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041390